Attorney's Docket No. 5784-25 (35784/172864)



RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITE PROCEDURE - EXAMINING GROUP 165

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Shirley et al.

Confirmation No.: 3829

Appl. No.:

09/188,051

Group Art Unit: 1653

Filed:

November 6, 1998

Examiner:

Kam, Chih-Min

For:

COMPOSITIONS PROVIDING FOR INCREASED IGF-I SOLUBILITY

November 27, 2002

BOX AF

Commissioner for Patents Washington, DC 20231

SUPPLEMENTAL AMENDMENT AFTER FINAL ACTION

Sir:

Responsive to the Advisory Action of September 24, 2002, and supplemental to the Amendment filed September 3, 2002, in response to the Final Office Action of May 31, 2002, the Examiner is respectfully requested to enter the following amendments into the above-referenced application.

In the Claims:

Please amend claims 29, 31, 46, 85, 99, and 101 to read as follows:

(Amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

- biologically active insulin-like growth factor-1 (IGF-I) or (a) biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C; and
- a solubilizing compound domprising a guanidinium group, wherein said solubilizing compound is present in said composition in an amount sufficient to